CDPH Study Closure

Please complete this form when all study activities have concluded.

Additionally, submit a final report (which can be a published article based on the research; a report prepared for the institution that funded or sponsored the research; a thesis or dissertation based on the research). Send to CDPHIRB@cityofchicago.org.

Project IRB#:
Project Title:
Approval Expiration Date:
Principal Investigator:

PI Telephone:	**PI E-mail**:	
Primary Contact:	**Telephone**:	**E-mail:**
Study start date:	**Study end date:**	

1. Project Status (Check one)

☐	Study completed (enrollment, treatment, data collection, follow-up, & data analysis are complete) *Please complete remainder of form.*
☐	Study was started but closed prior to completion and no further data collection (including long-term follow-up or re-contact) is planned. *Please explain why and complete remainder of form:*
☐	Study was never started and participants never enrolled or data collected. *Please explain why*

2. Storage and Data Closeout

A.	Was there a Data Use Agreement with CDPH associated with this study?	Yes ☐ No ☐
B.	If yes, have all requirements of the DUA been met, including (if applicable) returning all datasets or certify in writing the destruction of all data elements that could directly or indirectly identify individuals whose records were disclosed for the research as soon as the purposes of the research have been accomplished.	Yes ☐ No ☐ N/A ☐
C.	Has data been de-identified? (There is no identifiable protected health information or individually identifiable information being maintained or analyzed.) *If not, please answer the next two questions.*	Yes ☐ No ☐ N/A ☐
D.	Is data being maintained such that identifiers are separated from protected health information (or other individually identifiable information) via the use of a coding system AND no additional research planned beyond the original intent for this data? If yes, how long do you intend to keep the link to the PHI identifiers or individually identifiable information?	Yes ☐ No ☐ N/A ☐

E.	Is data being maintained and/or analyzed such that identifiers are NOT separated from protected health information (or individually identifiable information)	Yes ☑ No ☑
F.	Is there a plan for continued or future research other than the original intent using the data obtained? *If yes, please explain:* _____ _____ _____ (If yes, this study will remain open for ongoing review. If new hypothesis or study goals are developed, study will require new IRB review.)	Yes ☑ No ☑

3. Study Summary

A.	Please summarize the results of the study below, including any plans for scientific presentations or publication: _____ _____ _____ _____	
B.	Have there been any significant new findings or other information that should be provided to participants? *If yes, describe plans to share information:* _____ _____ _____ _____	Yes ☐ No ☐
C.	Was there a Data Safety Monitoring Board (DSMB) assigned to this study? *If yes, provide copies of any relevant DSMB reviews.* _____ _____ _____ _____	Yes ☐ No ☐

4. Participant Enrollment ***(For studies with primary data collection only. Skip this item if research involved secondary data analysis only.)***

A.	Total number of subjects enrolled: _____ _____% females _____ % males _____% non-Binary	
B.	Approximate racial and ethnic composition of enrolled subjects:	
	_____ % White _____ % Asian _____ % African American/Black	_____ % American Indian/Alaska Native _____ % Native Hawaiian/Pacific Islander _____ % Hispanic/Latinx _____ % Other (specify):
C.	During the course of the study, did any participants withdraw from the research?	Yes ☐ No ☐
	If yes, please explain why: _____ _____ _____	
D.	During the course of the study, were any complaints made by participants about the research?	Yes ☐ No ☐
	If yes, please explain why: _____ _____ _____	

5. Update on Research Risks

A.	Since the last IRB review, were there any interim findings that might alter the risks or benefits? *If yes, please explain:* _____ _____	Yes ☐ No ☐
B.	Since the last IRB review, did the risks or benefits change that may affect participants or the data collected? *If yes, please explain:* _____ _____	Yes ☐ No ☐
C.	Since the last IRB review, were there any unanticipated problems, adverse events, or protocol deviations that were related or possibly related to the study? *If yes, please complete and submit the CDPH Unanticipated Problems and/or Adverse Events form along with this document. If this form was previously submitted, please attach a copy of that form to this document.*	Yes ☐ No ☐

Principal Investigator Assurance

I certify that the information provided in this document is complete and accurate and that:

- Subjects are no longer being treated, followed, or participating in any other activities related to the research.
- All data has been gathered, analyzed, and disseminated, and that the disposition of the data is as specified as above.
- The final report or publication are complete.

_____ _____

Principal Investigator Signature **Date**

_____

Print Principal Investigator Name